

We claim:

1. A composition for preserving biological specimens consisting of:
 - a. an anti-coagulating agent, and
 - b. a stabilizing agent.
- 5 2. The composition of Claim 1, wherein said anti-coagulating agent is a chelating agent.
3. The composition of Claim 2, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA).
- 10 4. The composition of Claim 1, wherein said anti-coagulating agent is a complexing agent.
5. The composition of Claim 4, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
6. The composition of Claim 1, wherein said stabilizing agent is a formaldehyde donor.
- 15 7. The composition of Claim 6, wherein said formaldehyde donor is selected from the group consisting of: methylol or hydroxymethyl derivatives of amines or amides, diazolinidinyl urea, imidazolidinyl urea, methenamine, and paraformaldehyde.
8. The composition of Claim 1, wherein said stabilizing agent is an aldehyde.
9. The composition of Claim 8, wherein said aldehyde is selected from the group consisting of: formaldehyde, glutaraldehyde, and glyoxal.
- 20 10. The composition of Claim 1, wherein said stabilizing agent is a formaldehyde donor or an aldehyde combined with at least one heavy metal element.
11. The composition of Claim 10, wherein said heavy metal element is selected from the group consisting of: chromium, manganese, and zinc.
- 25 12. The composition of Claim 1, wherein an additional stabilizing agent is polyethylene glycol.
13. The composition of Claim 12, wherein the molecular weight of said polyethylene glycol is in the range of about 1000 to about 35000.
14. The composition of Claim 12, wherein the molecular weight of said polyethylene glycol is in the range of about 5000 to about 20000.
- 30 15. The composition of Claim 12, wherein the molecular weight of said polyethylene glycol is in the range of about 8000 to about 20000.

16. A composition for preserving blood samples suspected to contain circulating tumor cells consisting of:
- a. an anti-coagulating agent, and
 - b. a stabilizing agent.
- 5 17. The composition of Claim 16, wherein said anti-coagulating agent is a chelating agent.
18. The composition of Claim 17, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and
- 10 ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..
19. The composition of Claim 16, wherein said anti-coagulating agent is a complexing agent.
20. The composition of Claim 19, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
- 15 21. The composition of Claim 16, wherein said stabilizing agent is a formaldehyde donor.
22. The composition of Claim 21, wherein said formaldehyde donor is selected from the group consisting of: methylol or hydroxymethyl derivatives of amines or amides, diazolinidinyl urea, imidazolidinyl urea, methenamine, and paraformaldehyde.
23. The composition of Claim 16, wherein said stabilizing agent is an aldehyde.
- 20 24. The composition of Claim 23, wherein said aldehyde is selected from the group consisting of: formaldehyde, glutaraldehyde, and glyoxal.
25. The composition of Claim 16, wherein said stabilizing agent is a formaldehyde donor or an aldehyde combined with at least one heavy metal element.
26. The composition of Claim 25, wherein said heavy metal element is selected from the
- 25 group consisting of: chromium, manganese, and zinc.
27. The composition of Claim 16, wherein an additional stabilizing agent is polyethylene glycol.
28. The composition of Claim 27, wherein the molecular weight of said polyethylene glycol is in the range of about 1000 to about 35000.
- 30 29. The composition of Claim 27, wherein the molecular weight of said polyethylene glycol is in the range of about 5000 to about 20000.
30. The composition of Claim 27, wherein the molecular weight of said polyethylene glycol is in the range of about 8000 to about 20000.

31. A stabilized cell composition consisting of:
- a. a biological specimen,
 - b. an anti-coagulating agent, and
 - c. a stabilizing agent.
- 5 32. The stabilized cell composition of Claim 31, wherein said biological specimen is a fraction of blood suspected to contain circulating tumor cells.
33. The stabilized cell composition of Claim 32, wherein said circulating tumor cells have been stabilized by said stabilizing agent.
34. The stabilized cell composition of Claim 31, wherein said anti-coagulating agent is a
10 chelating agent.
35. The stabilized cell composition of Claim 34, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..
- 15 36. The stabilized cell composition of Claim 31, wherein said anti-coagulating agent is a complexing agent.
37. The stabilized cell composition of Claim 36, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
38. The stabilized cell composition of Claim 31, wherein said stabilizing agent is a
20 formaldehyde donor.
39. The stabilized cell composition of Claim 38, wherein said formaldehyde donor is selected from the group consisting of: methylol or hydroxymethyl derivatives of amines or amides, diazolinidiny l urea, imidazolidiny l urea, methenamine, and paraformaldehyde.
- 25 40. The stabilized cell composition of Claim 31, wherein said stabilizing agent is an aldehyde.
41. The stabilized cell composition of Claim 40, wherein said aldehyde is selected from the group consisting of: formaldehyde, glutaraldehyde and glyoxal.
42. The stabilized cell composition of Claim 31, wherein said stabilizing agent is
30 formaldehyde donor or an aldehyde combined with at least one heavy metal element.
43. The stabilized cell composition of Claim 42, wherein said heavy metal element is selected from the group consisting of: chromium, manganese, and zinc.
44. The stabilized cell composition of Claim 31, wherein an additional stabilizing agent is polyethylene glycol.

45. The stabilized cell composition of Claim 44, wherein the molecular weight of said polyethylene glycol is in the range of about 1000 to about 35000.
46. The stabilized cell composition of Claim 44, wherein the molecular weight of said polyethylene glycol is in the range of about 5000 to about 20000.
- 5 47. The stabilized cell composition of Claim 44, wherein the molecular weight of said polyethylene glycol is in the range of about 8000 to about 20000.
48. The stabilized cell composition of Claim 31, wherein said anti-coagulating agents and said stabilizing agents are present in volumes of about 0.1 to about 50% of the total volume of said biological specimen.
- 10 49. The stabilized cell composition of Claim 47, wherein said volumes are in the range of about 0.3 to about 30% of the total volume of said biological specimen.
50. The stabilized cell composition of Claim 47, wherein said volumes are in the range of about 0.3 to about 5% of the total volume of said biological specimen.
- 15 51. A method for preserving biological specimens consisting of:
- a. obtaining a biological specimen that contains cells, and
 - b. contacting said biological specimen with a stabilizing agent capable of stabilizing said cells.
52. The method of Claim 51, wherein said stabilizing agent is a formaldehyde donor.
- 20 53. The method of Claim 52, wherein said formaldehyde donor is selected from the group consisting of: methylol or hydroxymethyl derivatives of amines or amides, diazolinidinyl urea, imidazolidinyl urea, methenamine, and paraformaldehyde.
54. The method of Claim 51, wherein said stabilizing agent is an aldehyde.
55. The method of Claim 54, wherein said aldehyde is selected from: formaldehyde, glutaraldehyde, and glyoxal.
- 25 56. The method of Claim 51, wherein said stabilizing agent is formaldehyde donor or an aldehyde combined with at least one heavy metal element.
57. The method of Claim 56, wherein said heavy metal element is selected from the group consisting of: chromium, manganese, and zinc.
- 30 58. The method of Claim 51, wherein an additional stabilizing agent is polyethylene glycol.
59. The method of Claim 58, wherein the molecular weight of said polyethylene glycol is in the range of about 1000 to about 35000.

60. The method of Claim 58, wherein the molecular weight of said polyethylene glycol is in the range of about 5000 to about 20000.
61. The method of Claim 58, wherein the molecular weight of said polyethylene glycol is in the range of about 8000 to about 20000.
- 5 62. The method of Claim 51, wherein said specimen is further contacted with an anti-coagulating agent.
63. The method of Claim 62, wherein said anti-coagulating agent is a chelating agent.
64. The method of Claim 63, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine
10 pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..
65. The method of Claim 62, wherein said anti-coagulating agent is a complexing agent.
66. The method of Claim 65, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
- 15 67. The method of Claim 62, wherein said anti-coagulating agent and said stabilizing agent are combined before contacting said biological specimen.
68. The method of Claim 67, wherein said anti-coagulating agent is a chelating agent.
69. The method of Claim 68, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine
20 pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..
70. The method of Claim 67, wherein said anti-coagulating agent is a complexing agent.
71. The method of Claim 70, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
- 25 72. The method of Claim 67, wherein said anti-coagulating agents and said stabilizing agents are present in volumes of about 0.1 to about 50% of the total volume of said biological specimen.
73. The method of Claim 72, wherein said volumes are in the range of about 0.3 to about 30% of the total volume of said biological specimen.
- 30 74. The method of Claim 72, wherein said volumes are in the range of about 0.3 to 5% of the total volume of said biological specimen.
75. A method for preserving blood samples suspected to contain circulating tumor cells consisting of:

- a. obtaining a biological specimen that contains cells, and
 - b. contacting said biological specimen with a stabilizing agent capable of stabilizing said cells.
76. The method of Claim 75, wherein said stabilizing agent is a formaldehyde donor.
- 5 77. The method of Claim 76, wherein said formaldehyde donor is selected from the group consisting of: methylol or hydroxymethyl derivatives of amines or amides, diazolinidinyl urea, imidazolidinyl urea, methenamine, and paraformaldehyde.
78. The method of Claim 75, wherein said stabilizing agent is an aldehyde.
79. The method of Claim 78, wherein said aldehyde is selected from the group consisting of: formaldehyde, glutaraldehyde, and glyoxal.
- 10 80. The method of Claim 75, wherein said stabilizing agent is formaldehyde donor or an aldehyde combined with at least one heavy metal element.
81. The method of Claim 80, wherein said heavy metal element is selected from the group consisting of: chromium, manganese, and zinc.
- 15 82. The method of Claim 75, wherein an additional stabilizing agent is polyethylene glycol.
83. The method of Claim 82, wherein the molecular weight of said polyethylene glycol is in the range of about 1000 to about 35000.
84. The method of Claim 82, wherein the molecular weight of said polyethylene glycol is in the range of about 5000 to about 20000.
- 20 85. The composition of Claim 82, wherein the molecular weight of said polyethylene glycol is in the range of about 8000 to about 20000.
86. The method of Claim 75, wherein said specimen is further contacted with an anti-coagulating agent.
- 25 87. The method of Claim 86, wherein said anti-coagulating agent is a chelating agent.
88. The method of Claim 87, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..
- 30 89. The method of Claim 86, wherein said anti-coagulating agent is a complexing agent.
90. The method of Claim 89, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
91. The method of Claim 86, wherein said anti-coagulating agent and said stabilizing agent are combined before contacting said biological specimen.

92. The method of Claim 91, wherein said anti-coagulating agent is a chelating agent.
93. The method of Claim 92, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..
94. The method of Claim 91, wherein said anti-coagulating agent is a complexing agent.
95. The method of Claim 93, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
96. The method of Claim 86, wherein said anti-coagulating agents and said stabilizing agents are present in volumes of about 0.1 to about 50% of the total volume of said biological specimen.
97. The method of Claim 96, wherein said volumes are in the range of about 0.3 to about 30% of the total volume of said biological specimen.
98. The method of Claim 96, wherein said volumes are in the range of about 0.3 to about 5% of the total volume of said biological specimen.
99. An apparatus for preserving biological specimens consisting of an evacuated blood draw tube, said tube containing:
- a. an anti-coagulating agent, and
 - b. a stabilizing agent.
100. The apparatus of Claim 99, wherein said anti-coagulating agent is a chelating agent.
101. The apparatus of Claim 100, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..
102. The apparatus of Claim 99, wherein said anti-coagulating agent is a complexing agent.
103. The apparatus of Claim 102, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
104. The apparatus of Claim 99, wherein said stabilizing agent is a formaldehyde donor.
105. The apparatus of Claim 104, wherein said formaldehyde donor is selected from the group consisting of: methylol or hydroxymethyl derivatives of amines or amides, diazolinidinyl urea, imidazolidinyl urea, methenamine, and paraformaldehyde.
106. The apparatus of Claim 99, wherein said stabilizing agent is an aldehyde.

107. The apparatus of Claim 106, wherein said aldehyde is selected from the group consisting of: formaldehyde, glutaraldehyde, and glyoxal.
108. The apparatus of Claim 99, wherein said stabilizing agent is formaldehyde donor or an aldehyde combined with at least one heavy metal element.
- 5 109. The apparatus of Claim 108, wherein said heavy metal element is selected from the group consisting of: chromium, manganese, and zinc.
110. The apparatus of Claim 99, wherein said stabilizing agent has been lyophilized.
111. The apparatus of Claim 99 wherein an additional stabilizing agent is polyethylene glycol.
- 10 112. The apparatus of Claim 111, wherein the molecular weight of said polyethylene glycol is in the range of about 1000 to about 35000.
113. The apparatus of Claim 112, wherein the molecular weight of said polyethylene glycol is in the range of about 5000 to about 20000.
114. The apparatus of Claim 112, wherein the molecular weight of said polyethylene glycol is in the range of about 8000 to about 20000.
- 15 115. The apparatus of Claim 111, wherein said additional stabilizing agent has been lyophilized.
116. The apparatus of Claim 99, wherein said anti-coagulating agents and said stabilizing agents are present in volumes of about 0.1 to about 50% of the total volume of said draw tube.
- 20 117. The apparatus of Claim 116, wherein said volumes are in the range of about 0.3 to about 30% of the total volume of said draw tube.
118. The apparatus of Claim 116, wherein said volumes are in the range of about 0.3 to about 5% of the total volume of said draw tube.
- 25 119. An apparatus for preserving blood samples suspected to contain circulating tumor cells consisting of an evacuated blood draw tube containing:
- a. an anti-coagulating agent, and
 - b. a stabilizing agent.
- 30 120. The apparatus of Claim 119, wherein said anti-coagulating agent is a chelating agent.
121. The apparatus of Claim 120, wherein said anti-coagulating agent is selected from the group consisting of: ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DTPA), 1,2-diaminocyclohexane tetraacetic acid (DCTA), and ethylenebis(oxyethylenenitrilo) tetraacetic acid (EGTA)..

122. The apparatus of Claim 119, wherein said anti-coagulating agent is a complexing agent.
123. The apparatus of Claim 122, wherein said anti-coagulating agent is selected from the group consisting of heparin and citrate.
- 5 124. The apparatus of Claim 119, wherein said stabilizing agent is a formaldehyde donor.
125. The apparatus of Claim 123, wherein said formaldehyde donor is selected from the group consisting of: methylol or hydroxymethyl derivatives of amines or amides, diazolinidinyl urea, imidazolidinyl urea, methenamine, and paraformaldehyde.
126. The apparatus of Claim 119, wherein said stabilizing agent is an aldehyde.
- 10 127. The apparatus of Claim 126, wherein said aldehyde is selected from the group consisting of: formaldehyde, glutaraldehyde, and glyoxal.
128. The apparatus of Claim 119, wherein said stabilizing agent is formaldehyde donor or an aldehyde combined with at least one heavy metal element.
129. The apparatus of Claim 128, wherein said heavy metal element is selected from the group consisting of: chromium, manganese, and zinc.
- 15 130. The apparatus of Claim 119, wherein said stabilizing agent has been lyophilized.
131. The apparatus of Claim 119, wherein an additional stabilizing agent is polyethylene glycol.
132. The apparatus of Claim 131, wherein the molecular weight of said polyethylene glycol is in the range of about 1000 to about 35000.
- 20 133. The apparatus of Claim 131, wherein the molecular weight of said polyethylene glycol is in the range of about 5000 to about 20000.
134. The apparatus of Claim 131, wherein the molecular weight of said polyethylene glycol is in the range of about 8000 to about 20000.
- 25 135. The apparatus of Claim 131, wherein said additional stabilizing agent has been lyophilized.
136. The apparatus of Claim 119, wherein said anti-coagulating agents and said stabilizing agents are present in volumes of about 0.1 to about 50% of the total volume of said draw tube.
- 30 137. The apparatus of Claim 136, wherein said volumes are in the range of about 0.3 to about 30% of the total volume of said draw tube.
138. The apparatus of Claim 136, wherein said volumes are in the range of about 0.3 to about 5% of the total volume of said draw tube.

139. The composition of Claim 1, wherein an additional stabilizing agent is polyethylene glycol at a concentration of about 0.1% to about 5%, preferably about 0.1% to about 1%, and most preferably about 0.1% to about 0.5% of the specimen volume.
140. The composition of Claim 16, wherein an additional stabilizing agent is polyethylene glycol at a concentration of about 0.1% to about 5%, preferably about 0.1% to about 1%, and most preferably about 0.1% to about 0.5% of the specimen volume.
141. The stabilized cell composition of Claim 31, wherein an additional stabilizing agent is polyethylene glycol at a concentration of about 0.1% to about 5%, preferably about 0.1% to about 1%, and most preferably about 0.1% to about 0.5% of the specimen volume.
142. The method of Claim 51, wherein an additional stabilizing agent is polyethylene glycol at a concentration of about 0.1% to about 5%, preferably about 0.1% to about 1%, and most preferably about 0.1% to about 0.5% of the specimen volume.
143. The method of Claim 75, wherein an additional stabilizing agent is polyethylene glycol at a concentration of about 0.1% to about 5%, preferably about 0.1% to about 1%, and most preferably about 0.1% to about 0.5% of the specimen volume.
144. The apparatus of Claim 99, wherein an additional stabilizing agent is polyethylene glycol at a concentration of about 0.1% to about 5%, preferably about 0.1% to about 1%, and most preferably about 0.1% to about 0.5% of the specimen volume.
145. The apparatus of Claim 119, wherein an additional stabilizing agent is polyethylene glycol at a concentration of about 0.1% to about 5%, preferably about 0.1% to about 1%, and most preferably about 0.1% to about 0.5% of the specimen volume.